



10/692,338

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Terri L. Butler et al.

Examiner: Traviss C. McIntosh, III

Serial Number: 10/692,338

Group art unit: 1623

Filed: 23 October 2003

Docket: BP.028US2

Title: COMPOSITIONS AND METHODS FOR
IMPROVING CARDIOVASCULAR FUNCTION

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents

P.O. Box 1450

Alexandria, VA, 22313-1450

I, John A. St. Cyr, hereby declare as follows:

1. I am a joint inventor of the above referenced invention. I have received the following degrees from the University of Minnesota: BA, 1973; BS, 1975; MS, 1977; MD, 1980; Ph.D., 1988. In addition, I completed a residency in General Surgery at the University of Minnesota in 1988 and a residency in Cardiovascular Surgery at the University of Colorado in 1991. Since 1991, I have been an independent consultant in research for various companies, investigating cardiovascular methods and devices, including energy metabolism. Since 1995, I have consulted with Bioenergy, Inc., the assignee of this patent application, where I am Medical Director and a minority shareholder.

During the period of my Ph.D. studies, I began working in the laboratory of Dr. John E. Foker, investigating potential adenine nucleotide improvement following myocardial ischemia. Some of the findings are included in the Foker Patent (4,719,201). I have published over 100 scientific papers and abstracts, about 30 of which relate to ATP metabolism. Two of these papers are of record in this case.

2. In the Office Action of 11/14/2008, Examiner McIntosh has rejected pending

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claims 1-3 and 6 under U.S.C. 103 (a) on the grounds of obviousness over Omran et al.(of record) in view of St. Cyr, et al. (U.S. Patent 6,218,366). The Examiner points out that the Omran et al. reference was published before the 102(a) effective reference date of the present application. I respectfully disagree and herein explain why the present invention is not obvious from the prior art and why it was not known to another before the invention was made.

3. In the absence of other information, the effective filing data is considered to be the date of invention under 102(a). This assumption can be refuted by evidence of when the invention was made. It can be noted that I am both an inventor of the present invention and a co-author of the Omran et al. reference.

4. The creative concept resulting in the invention was made by myself, Dr. Terri Butler and Clarence Johnson beginning in 2000. The first provisional application, SN 60/221,526, filed July 28 2000, was an early inventive concept which has been continued and added to in the subsequent provisional application, SN60/302,200, filed June 29, 2001. The concept that D-ribose was the key and required composition was explained in the first provisional application, showing that the inventive concept was developed nearly a year before the reference abstract.

5. We three inventors developed the inventive concept into a clinical protocol that would reduce the concept to practice. After the protocol was completed, shortly after the first provisional application was filed on July 28, 2000, Dr. Heyder Omran was contacted to perform the clinical study according to our protocol, which was submitted and approved by the German equivalent of the Institutional Review Board. Once approved, a protocol cannot be changed. Dr. Omran was not part of the discussions leading to the inventive concept or the protocol and did not know of any effects of ribose on cardiac rehabilitation prior to communication with me and the other inventors of the present application. When his study was completed, I wrote the abstract that is the Omran et al. reference. At the same time, a complete manuscript was prepared, and incorporated into the present application as proof of efficacy of the inventive concept. I submit that the correct 102 (a) date of invention was prior to or shortly after July 28, 2000, before any person other than the inventors knew of the invention.

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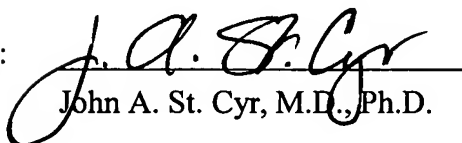
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6. Dr. Omran worked under my direction and control, followed the protocol supplied to him and reported the results to me. The other authors of the reference assisted with the data analysis and summary of results. I wrote the Omran et al. reference and the subsequent manuscript. These results comprise the experimental data of the present invention. Dr. Omran and the other coauthors were not listed as inventors because they did not contribute to the inventive concept of the invention.

I hereby declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By:


John A. St. Cyr, M.D., Ph.D.

Date: January 14, 2009